Prepared Remarks
Professor Marsha N. Cohen
Hastings College of the Law (University of California)
Public Meeting, Health Claims in Dietary Supplement Labeling
Washington, D.C.
April 4, 2000

I've spent much time during the past week wondering why I agreed to come to this meeting, at least since my original invitation to speak as part of Panel II was modified to place me on Panel III. I've been wondering what I could possibly contribute, since I basically don't agree with the premise of the debate here today, namely that there is a First Amendment barrier to setting minimum standards for claims made on the labels of government-regulated products. Note that I've projected the dictum of the *Pearson* court beyond food supplements, as there is a whole host of government-regulated products in the marketplace to which its notions could apply.

As a law professor it is part of my job description to deconstruct and criticize judicial decisions, and *Pearson* leaves much room for both. I've decided to express my thoughts on this topic briefly, even though they are off the declared subject, because we need to consider the exact task that FDA has been presented by the court. FDA has already met one of the court's concerns. Although for two years as part of the Keystone dialogue on significant scientific agreement I did not perceive that anyone with a science background was confused by the meaning of that standard, it may be unclear to the lawyers. But it is unclear no more, given the agency's guidance on this subject. As to the application of that now-well-articulated standard to the evidence presented for the four sets of claims at issue, that is beyond my competence; I assume that FDA will be revisiting the evidence and providing adequate explanation of its conclusions.

The First Amendment dicta are troubling, for a number of reasons. Let me note that I am no expert on the First Amendment. I am troubled that the FDA did not raise one of its most potent arguments at the appropriate time, and thus it was not heard. It was Congress, after all, that decided that there ought to be some circumscribed exceptions to the drug approval provisions of the Food, Drug, and Cosmetic Act to meet, as it said, the "growing need for emphasis on the dissemination of information linking nutrition and long-term good health." Congress thus devised a regulatory scheme that allows food supplements to bear health claims that prior to the legislation would have caused the products to be regulated as drugs; the "significant scientific agreement" standard is Congress's creation. The court considered drugs to be "in an entirely different category" than food supplements, notwithstanding its recognition of the new law as creating a "safe harbor" from drug status for supplements bearing approved health claims. In fact there is considerable potential for overlap; food supplements, to the extent that they make certain claims, are legally drugs.

I'm also troubled by the analysis applying the First Amendment to the issues in this case. The much-cited *Central Hudson* case in fact provides that the "government may ban forms of communication more likely to deceive the public than to inform it." It may well be that

advertising will rarely fall into this category; the significant cases upon which the *Pearson* court relies all involve advertising. Furthermore, some of the critical cases, such as *44 Liquormart*, involve bans on the advertising of very basic factual information, such as prices, the objective truth of which can be fairly easily determined. But we are here concerned with the food and drug product label, a highly regulated space where there are required disclosures, in mandatory formats, even with type size requirements. Consumer expectations about information conveyed in that space are, I am certain, quite different than about advertising. And we are dealing with information, claims, the objective truth of which cannot be easily determined by the consumer.

But the shortcomings of *Pearson* are not our primary focus. The boundary line between drug claims and other claims is our topic. I should state that I wish that Congress never started down this path, and I am quite skeptical that even "reducing the risk of" claims are read in limited fashion. If these products could move beyond risk reduction to mitigation or treatment claims, the public would be disserved. While some consumers purchase food supplements as preventive medicine, many others are turning to supplements as alternative medicine, hoping to obtain drug-like benefits without the perceived far-greater side effects. There may well be a lot of legitimate benefits from the world of herbal and other supplement products as alternative medicine, but those products should be subject to a regulatory regime at least similar to that imposed on more traditional drugs in order to assure consumers equivalent protections. There should be not only adequate evidence of their safety and efficacy, but also assurance that the dosages are properly recommended, that there is product-to-product and sample-to-sample bioequivalence, that good manufacturing practices are followed, and that prescription requirements are considered.

The current regulatory scheme falls far short, and is in many ways the worst of all possible worlds. In *The Washington Post National Weekly Edition* for March 27, 2000, an official of California's Department of Health Services characterizes the supplement scene as "like the wild, wild west," and I wholeheartedly agree. FDA doesn't even know about many of the products making claims; FDA has insufficient manpower to assure that the claims made are substantiated; skepticism that such substantiation exists is surely justified.

Yet some herbal products could be good medicine. I understand that St. John's wort is the most frequently-prescribed antidepressant in Germany, with a lower risk profile than its traditional antidepressant competitors. This fact is hardly lost on American consumers, who read the structure/ function claim on St. John's wort — "may help enhance mood" — and draw the obvious and intended conclusion about its medical purpose. Yet a claim that St. John's wort mitigates or treats depression should not be allowed today, because that is clearly a drug claim, and this supplement is not being regulated as a drug. I would be pleased if there were a statutory means for alternative medicine products that meet drug standards of safety and efficacy to obtain approval as drugs, without each seller having to obtain an individual NDA. Each seller should have to demonstrate compliance with GMP, dosage, labeling, and similar requirements, under a "master approval," like the food additive petition. Some supplement products so approved might need to be covered by prescription requirements, although most probably would meet the criteria for over-the-counter sale.

I appreciate the FDA's attempt to deal with the semantics of what is a structure/function claim and what is a drug claim. I doubt its careful distinctions are appreciated by the typical readers of the claims. I would like to see some research about what exactly is communicated by the various claims; if what is communicated is in the nature of a drug claim, then the full panoply of patient protections in our law and regulations should apply. The public expects and deserves no less.